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**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| **IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION**<br><br>**This Document Relates To:**<br><br>*Stout, et. al. v. New England Compounding Pharmacy, Inc., et. al.*, No. 13-cv-10167 | **MDL No. 1:13-md-02419**<br><br>**Hon. F. Dennis Saylor, IV**<br><br>*Leave to File Brief in Excess of 20 Page Limit Under Local Rule 7.1(b)(4) Granted on February 25, 2013 [Docket No. 10]* |

**MEMORANDUM IN SUPPORT OF ALAUNUS PHARMACEUTICAL, LLC'S MOTION TO DISMISS PURSUANT TO FED.R.CIV.P. 12(B)(6)**

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## I. INTRODUCTION

Plaintiff, Julia Stout, as Personal Representative of the Estate of James Robert Stout, individually and on behalf of others similarly situated, bring this product liability action against New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), Ameridose, LLC ("Ameridose"), Alaunus Pharmaceutical, LLC ("Alaunus"), Medical Sales Management, Inc. ("MSM"), Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry J. Cadden, Lisa Cadden, and Glenn Chin. Plaintiff's Complaint asserts various causes of action collectively against the Defendants arising out of alleged injuries suffered by Mr. Stout as a result of exposure to an allegedly contaminated steroid product, methylprednisolone acetate ("MPA"), compounded by NECC. Plaintiff's Complaint is in eight (8) counts: Count I – Negligence; Count II – Negligent Infliction of Emotional Distress; Count III – Breach of Express and Implied Warranties; Count IV – Battery; Count V – Failure to Warn; Count VI – Loss of Consortium; Count VII – Limited Fund Constructive Trust; and, Count VIII – Wrongful Death. *See id.*, generally.

The MPA product, around which this litigation revolves, is an injectable steroid often used for pain management, is only available to licensed healthcare providers, and was compounded and distributed by NECC in Framingham, Massachusetts. On September 26, 2012, NECC initiated a nationwide recall of the MPA product after the Food and Drug Administration ("FDA") and the U.S. Centers for Disease Control and Prevention ("CDC") investigated multiple state reports of fungal meningitis among patients whom received an epidural steroid injection from one of three lots of MPA compounded in 2012 at NECC. NECC voluntarily ceased operations, surrendered its license to the Massachusetts Board of Registration in Pharmacy on October 3, 2012, and subsequently initiated a voluntary recall of all its products. On December 21, 2012, NECC filed for bankruptcy.

This case should be dismissed as to Alaunus for multiple reasons. As an initial matter, all of the allegations against Alaunus are merely conclusory assertions and the Complaint does not provide Alaunus with adequate notice of the factual basis of the liability asserted. The statement in the

Complaint that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose," *Pl. Compl.* at ¶ 11, is not a "fact" which must be taken as true on a 12(b)(6) motion because it is merely a formulaic recitation of the definition of a "manufacturer" and "seller" under the IPLA and the Complaint does not contain any factual allegations *showing* that Alaunus is a "manufacturer" or "product seller" within the meaning of the statute. Plaintiffs do not plead sufficient facts, as opposed to conclusory assertions, to show that Alaunus is vicariously liable for NECC's alleged tortious conduct under an alter-ego liability theory. Each Complaint impermissibly "lumps" NECC, Ameridose, MSM, and Alaunus together and therefore does not provide those defendants with notice as to the specific basis of liability asserted against each individual defendant.

Moreover, the factual content in the Complaint, when taken as true, does not give rise to a plausible inference of liability against Alaunus. There is a true conflict of laws and Indiana law governs because that is the place where the injury occurred and Massachusetts does not have a more significant relationship to the underlying product liability claims in this case. Any claim that Mr. Stout may have had against Alaunus under Indiana's Product Liability Act ("IPLA") had he survived fails because Plaintiff has not shown that Alaunus is a "manufacturer" or "seller" of the MPA product as defined under the IPLA, or had any involvement whatsoever in that products' compounding, distribution, or marketing. The common law claims for negligence, negligent infliction of emotional distress, breach of express and implied warranties, battery, failure to warn, and loss of consortium are subsumed under the IPLA, and may not be sustained as separate actions against an alleged "manufacturer" or "seller." Even if those claims are not subsumed under the IPLA (which they are), the Complaint fails to plead sufficient facts to establish a viable claim under any of those theories of liability. In any event, any product liability claim that accrued in favor of Mr. Stout terminated at his death under Indiana's Survival Act, leaving Mrs. Stout with a claim under Indiana's General Wrongful Death Act. Given that the Complaint fails to state any viable claim against Alaunus on behalf of the

decedent, the loss of consortium and wrongful death claims should be dismissed because Mrs. Stout's claim for damage to the marital relationship is derived from the failed claims asserted by the decedent against Alaunus and the Complaint does not show that Mr. Stout's death was caused by a wrongful act or omission by Alaunus. Similarly, the claim for establishment of a limited fund constructive trust fails because there is no showing of any fraud, breach of fiduciary duty, or any other wrongful conduct by Alaunus. Finally, the claim for class certification fails for lack of predominance of factual and legal issues.

For these reasons, the Plaintiff's Complaint woefully fails to state a claim and should be dismissed in its entirety, or at the very least as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6)

## II. FACTUAL ALLEGATIONS IN THE COMPLAINT

While the Complaint directs the majority of the allegations towards NECC, the statements in the Complaint pertaining to Alaunus are quite thin. The Complaint states that Alaunus "is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business in Framingham, Massachusetts, next door to Defendant NECC." *Id.* at ¶ 11. While the Complaint asserts that Alaunus was founded "to market generic pharmaceutical products," *id.* at ¶ 32, the pleading also asserts that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose." *Id.* at ¶ 11. The Complaint continues that "Barry Cadden and Gregory Conigliaro are the majority shareholders in and own NECC, Ameridose, and Alaunus" and that "at all relevant times, Barry and Gregory operated NECC, Ameridose, and Alaunus, and were responsible for compounding, manufacturing, distributing, and selling the contaminated steroid injections at issue in this litigation." *Id.* at ¶ 20. Based upon common ownership with NECC, the Complaint states that the FDA and DPH inspected Alaunus' facility following NECC's recall. *Id.* at ¶ 41. Significantly, the Complaint does not assert that the inspection revealed any evidence indicating that Alaunus was involved in the manufacture, distribution, or sale of MPA. Nevertheless, Plaintiff

concludes, without factual support, that "there has existed a unity of interest in ownership between Defendants NECC, Ameridose, MSM, and Alaunus, such that any individuality and separateness between them has ceased, and each such entity is the alter ego of each other entity" and that "[a]dherence to the fiction of the separate existence of each such Defendant as an entity distinct from each other would permit an abuse of the corporate privilege, sanction fraud, and promote injustice." *Id.* at ¶ 21. Based on these allegations alone, Plaintiff refers to NECC, Ameridose, MSM and Alaunus collectively as the "Defendants" throughout the balance of the Complaint. *See Id.*, generally.

As to Mr. Stout's experience, the Complaint states that he had a "methylprednisolone acetate steroid injections in January 2012, to treat pain in his back and legs" and "received his second treatment on August 23, 2012, with subsequently recalled doses compounded and distributed by NECC in lots 05212012@68 and 06292012@26." *Id.* at ¶ 57. The Complaint states that "the August 2012 injections occurred at St. Mary's Medical Center in Evansville, Indiana and were administered by a licensed medical care provider pursuant to a prescription." *Id.* The Complaint continues that "[a] few weeks after the August 2012 injections, Mr. Stout began to experience symptoms of meningitis, and he entered Memorial Hospital and Health Care Center on September 23, 2012" where he passed away one month later. *Id.* at ¶ 58.

## III. STANDARD OF REVIEW

For a complaint to survive dismissal under Federal Rule of Civil Procedure 12(b)(6), it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). To have facial plausibility, the complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 1949 (2009). Although the plausibility standard is not akin to a probability requirement, Plaintiffs' factual allegations must show that the claim for relief is more than "speculative" or merely "conceivable" in order to show that the claim is "plausible on its face." *Twombly*, 550 U.S. at 555, 570

(holding that "[b]ecause the plaintiffs here have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed"). The First Circuit[1] has ruled that "if the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal." *Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 771 (1st Cir. 2011).

While all *well-pled* facts contained in the complaint should be accepted by the court as true on a 12(b)(6) motion to dismiss, "a plaintiff's obligation to provide the 'grounds' of [her] 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 129 S. Ct. at 1949; *Twombly*, 127 S.Ct. at 1965. The Court should not credit "conclusory assertions, subjective characterizations, or outright vituperation" on a 12(b)(6) motion. *Barrington Cove Ltd. Partnership v. Rhode Island Housing and Mortg. Finance Corp.*, 246 F.3d 1 (1st Cir. 2001). Naked assertions devoid of further factual enhancement in the complaint should not be deemed as true by the court. *Maldonado v. Fontanes*, 568 F.3d 263, 266 (1st Cir. 2009).

The First Circuit has interpreted *Twombly* and *Iqbal* as requiring a two-pronged approach after the Court takes note of the elements of the claim. *Grajales v. Puerto Rico Ports Authority*, 682 F.3d 40, 44 (2012), citing *Iqbal*, 556 U.S. at 678 - 679. To determine the sufficiency of a complaint under *Twombly* and *Iqbal*, the court should first "tak[e] note of the elements a plaintiff must plead to state a claim." *Iqbal*, 129 S.Ct. at 1947, 1950. Next, "the court must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." *Grajales*, 682 F.3d at 44, citing *Morales-Cruz v. Univ. of P.R.*, 676 F.3d 220, 224 (1st Cir.2012). Finally, the court must determine whether the factual content set forth in the complaint permits "the reasonable inference that the defendant is liable for the misconduct alleged." *Grajales*,

[1] When a diversity action is transferred pursuant to 28 U.S.C. § 1407, the transferee court is obligated to apply federal procedural law as interpreted by the United States Court of Appeals for the First Circuit, the circuit in which this transferee court sits. *See In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1178 (D.C. Cir. 1987), aff'd, 490 U.S. 122 (1989). *See also In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 368 n.8 (3d Cir. 1993) (assuming without deciding that the law of the § 1407 transferee district controls federal questions); *In re Auto. Refinishing Paint*, 229 F.R.D. 482, 486-87 (E.D. Pa. 2005) (applying transferee court's interpretation of federal law).

682 F.3d at 44 (internal quotation marks omitted), citing *Sepúlveda-Villarini v. Dep't of Educ. of P.R.*, 628 F.3d 25, 29 (1st Cir.2010) (Souter, J.) ("The make-or-break standard ... is that the combined allegations, taken as true, must state a plausible, not a merely conceivable, case for relief"). Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint should be dismissed because it has alleged—but it has not "shown"— "that the pleader is entitled to relief." *Iqbal*, 129 S.Ct. at 1950.[2]

## V. ARGUMENT

The Complaint should be dismissed because it: (1) contains nothing but conclusory assertions of liability against Alaunus which should be ignored by the Court; and, (2) Plaintiffs have not plead facts sufficient to support the causes of action alleged.

### 1. The Complaint contains nothing but conclusory assertions of liability against Alaunus which should be ignored by the Court.

The Complaint does not contain any factual allegations supporting the conclusion that Alaunus was involved in the manufacture or sale of MPA or the conclusion that Alaunus is merely an alter-ego of NECC. Additionally, the pleading does not contain an adequate factual basis to distinguish the conduct of Alaunus from that of the other co-defendants. Whereas the Complaint contains nothing but "naked" assertions of liability against Alaunus, such assertions should not be deemed as true by the Court and the claims against Alaunus should be dismissed pursuant to Fed.R.Civ.P. 12(b)(6).

#### a. The Complaint does not contain any factual allegations supporting the assertion that Alaunus was involved in the manufacture or sale of methylprednisolone acetate.

The statement in the Complaint that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose," *Pl. Compl.* at ¶ 11, is not a "fact" which must be taken as true by the Court on

[2] There is no question that *Twombly* and *Iqbal* apply to product liability cases. *See*, e.g., *Lewis v. Abbot Laboratories*, No. 08 Civ. 7480, 2009 WL 2231701 (S.D.N.Y. July 24, 2009) (Depakote); *Frey v. Novartis Pharmaceuticals Corp.*, No. C-1-07-317, 2009 U.S. Dist. Lexis (S.D. Ohio July 23, 2009) (Trileptal). Further, MDL courts have had no problem applying *Twombly* and *Iqbal*. *See*, e.g., *In re Guidant Corp., Implantable Defibrillators*, MDL No. 05-1708, 2009 WL 1921902 (D. Minn. July 1, 2009); *In re Bausch & Lomb Inc.*, MDL No. 1785, 2007 WL 3046682 (D. S.C. 2007).

a 12(b)(6) motion.

Various circuits have proposed tests for distinguishing "facts" from "conclusions" for pleading purposes. For example, in *The Dartmouth Review v. Dartmouth College*, the First Circuit stated that:

> "Most often, facts are susceptible to objective verification. Conclusions, on the other hand, are empirically unverifiable in the usual case. They represent the pleader's reactions to, sometimes called 'inferences from,' the underlying facts. It is only when such conclusions are logically compelled, or at least supported, by the stated facts, that is, when the suggested inference rises to what experience indicates is an acceptable level of probability, that 'conclusions' become 'facts' for pleading purposes."

889 F.2d 13, 16 (1st Cir. 1989). Similarly, the Third Circuit test distinguishes "facts" from "conclusions" by determining whether the statement is a pure question of fact (in which case the allegation must be accepted as true) or a pure question of law or a mixed question of fact and law (in which case the court should not accept the statement as true on a 12(b)(6) motion). *See Interfaith Cmty. Org. v. Honeywell Int'l, Inc.*, 399 F.3d 248, 269 (3rd Cir. 2005). A mixed question of fact and law can only be answered by both determining the facts of a case and determining what the relevant law means. *Id.*

Applying these tests for distinguishing "facts" from "conclusions," the courts have repeatedly held that allegations involving terms that a plaintiff must prove to sustain a cause of action and which are defined by statute or common law present mixed questions of fact and law and are therefore conclusory unless supported by independent factual allegations from which an inference may be drawn to support the stated conclusion. *See DM Research v. College of American Pathologists*, 170 F. 3d 53, 55 (1st Cir. 1999) (recognizing that terms like "conspiracy" or "agreement" are conclusory unless supported by independent factual allegations in the complaint); *TV Communications Network, Inc. v. Turner Network Television, Inc.*, 964 F.2d 1022, 1026 (10th Cir. 1992) (stating that "while TVCN uses antitrust language in its complaint, such as 'price fixing,' 'group boycott' and 'exclusionary measures,' it fails to elaborate on these allegations" and that "the use of antitrust 'buzz words' does not supply the

factual circumstances necessary to support TVCN's conclusory allegations").[3]

Similar to these kinds of assertions, the assertion that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose," is not a "fact" which must be deemed as true on a 12(b)(6) motion. The question of whether Alaunus may be held liable to the Plaintiffs depends, in part, on whether the Complaint asserts sufficient facts to *show* that it is a "manufacturer" or "seller," terms that have a specific meaning under the Indiana Product Liability Act. *See* Ind. Code § 34-6-2-77 (stating that a "manufacturer" is "a person or an entity that designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer"); Ind. Code § 34-6-2-136 (stating that a "seller" is defined as "a person engaged in the business of selling or leasing a product for resale, use, or consumption"). Thus, the question of whether Alaunus is a "manufacturer" or "seller" within the meaning of the IPLA is a mixed question of fact and law because it depends on an analysis of the relevant facts under the statutory definition of those terms to determine whether Alaunus qualifies as a party that may be held liable under the statute. *See Ohio State Bd. of Pharmacy v. Poppe*, 48 Ohio App.3d 222, 549 N.E.2d 541 (Ohio App. 1988) (stating that "naturally, in order to determine whether a person qualifies as a 'wholesale distributor of dangerous drugs,' the definition of that term must be consulted" under applicable state statute).

In short, the statement that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and

[3] *See also Bass v. E.I. DuPont de Nemours & Co.*, 324 F.3d 761, 765 (4th Cir. 2003) ("the words 'hostile work environment' are not talismanic, for they are but a legal conclusion; it is the alleged facts supporting those words, construed liberally, which are the proper focus at the motion to dismiss stage"); *Doe I v. Wal-Mart Stores, Inc.*, 572 F.3d 677, 683 (9th Cir. 2009) (holding allegation that Wal-Mart exercised "control" over day-to-day employment so as to constitute a joint employer was conclusory); *Holmes v. Poskanzer*, 342 F. App'x 651, 653 (2nd Cir. 2009) (holding that allegation that defendants were not "impartial" was conclusory and, without facts to support actual bias or conflict of interest, could not state due process claim); *Claudio v. Sawyer*, 675 F. Supp. 2d 403, 407–10 (S.D.N.Y. 2009) (holding allegation that off-duty officer was "acting under color of law" was conclusory in the absence of factual showing that officer was acting in capacity as police officer); *Delgado-O'Neil v. City of Minneapolis*, No. 08-4924 (MJD/JJK), 2010 WL 330322, at *10–11 (D. Minn. Jan. 20, 2010) (finding allegation that defendant took several adverse employment actions "in retaliation" for plaintiff's protected conduct were conclusory).

Ameridose" merely parrots back the definition of statutory terms under the IPLA. The Complaint does not contain any independent ***factual allegations*** to support the conclusion that Alaunus was a "manufacturer" or "seller" of MPA. Consequently, such statement is merely a "naked" assertion which should not be taken as true on a 12(b)(6) motion. *See Iqbal*, 129 S.Ct. at 1944 (finding that Iqbal's allegations that Ashcroft had served as the "principal architect" of a policy and that Mueller was "instrumental in adopting and executing" a policy subjecting Iqbal to harsh conditions of confinement on account of his race, religious, and national origin were conclusory assertions that need not be accepted as true on a 12(b)(6) motion); *In re Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (allegation that "Defendants, either directly or through [their] agents, apparent agents, servants, or employees, at all relevant times, designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax and Boniva" was conclusory since the complaint did not provide any specifics to support such a conclusion).[4]

**b. <u>There is No Basis to Disregard the Corporate Form of Alaunus Because the Plaintiff Pleads Only Conclusory Assertions in Support of The Claim for Alter-Ego Liability</u>.**

The Court should apply Massachusetts law of corporate disregard.[5] "Under Massachusetts

[4] Even if this Court were to find that the statement in the Complaint that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose" is a "fact" for pleading purposes (which it is not), the Court should still refuse to accept the statement as true because of the threadbare nature of the statement. *See Peñalbert-Rosa v. Fortuño-Burset*, 631 F.3d 592, 595 (1st Cir. 2011) (stating that "some allegations, while not stating ultimate legal conclusions, are nevertheless so threadbare or speculative that they fail to cross the line between the conclusory to the factual"); *Ocasio-Hernández v. Fortuño-Burset*, 640 F.3d 1, 12 (1st Cir. 2011) ("[a] plaintiff is not entitled to `proceed perforce' by virtue of allegations that merely parrot the elements of the cause of action").

[5] Most courts apply the law of the state of incorporation for veil piercing and alter-ego claims since corporations and LLCs are formed under the law of the state of incorporation. *See Patin v. Thoroughbred Power Boats, Inc.*, 294 F.3d 640, 647 (5th Cir.2002); *Judson Atkinson Candies, Inc. v. Latini–Hohberger Dhimantec*, 529 F.3d 371, 378 (7th Cir.2008); *Fletcher v. Atex, Inc.*, 68 F.3d 1451, 1456 (2nd Cir.1995). Whereas NECC, Ameridose, MSM and Alaunus are organized under Massachusetts law and have their principal places of business in this state, Massachusetts law of corporate disregard controls regardless of whether this Court follows the state of incorporation rule or applies Massachusetts' functional choice of law rules. *See Las Vegas Sands Corp. v. Ace Gaming, LLC*, 713 F.Supp.2d 427 (D. N.J. 2010) (applying New Jersey choice of law principles and holding that plaintiff's veil piercing and alter-ego law claims were governed by New Jersey law, notwithstanding that plaintiffs were Nevada corporations, because the entity whose veil plaintiff sought to pierce was incorporated under New Jersey law and the ultimate target of the veil piercing claim had a principal place of business in New Jersey). *See also Platten v. HG Berm. Exempted Ltd.*, 437 F.3d 118, 127 (1st Cir.2006) (applying Massachusetts' corporate disregard law because plaintiff filed suit in this state and therefore selected Massachusetts law).

common law, disregarding the corporate form is permissible only in rare situations." *United Elec., Radio and Mach. Workers v. 163 Pleasant St. Corp. (Pleasant St. I)*, 960 F.2d 1080, 1091 (1st Cir.1992) (citing *Pepsi-Cola Metro. Bottling Co. v. Checkers, Inc.*, 754 F.2d 10, 15-16 (1st Cir.1985)). In fact, "Massachusetts has been somewhat more `strict' than other jurisdictions in respecting the separate entities of different corporations." *Birbara v. Locke*, 99 F.3d 1233, 1238 (1st Cir.1996) (quoting the seminal case, *My Bread Baking Co. v. Cumberland Farms, Inc.*, 353 Mass. 614, 233 N.E.2d 748, 752 (1968)) (holding that the presumption of corporate separateness may be overcome only "in rare particular situations in order to prevent gross inequity").[6]

The only statements in the Complaint that relates to Plaintiff's alter-ego claim is that: (1) Alaunus' principal place of business is next door to NECC's place of business, *Pl. Compl.* at ¶ 11; (2) there is common ownership and management between NECC, Ameridose, and Alaunus, *id.* at ¶ 20. Common ownership and the proximity of the location of Alaunus' principal place of business do not support an inference under Massachusetts law that "any individuality and separateness between them has ceased." *See Evans v. Multicon Constr. Corp.*, 30 Mass.App.Ct. 728, 574 N.E.2d 395, 398-400, rev. denied, 410 Mass. 1104, 577 N.E.2d 309 (1991) (refusing to disregard the corporate form where the only four *My Bread* factors weighed in favor of piercing included common ownership, sharing of officers and employees, exertion of pervasive control, and the shareholders' use of the corporations in aid of the transactions in which they had an interest).[7] Consequently, this Court should ignore the

[6] In determining whether circumstances warrant the use of this "rare" measure, the court should undertake an inquiry into the actual nature of the corporate interrelationship to evaluate whether the "Pepsi-Cola factors" militate in favor of disregarding the corporate form. These factors are: (1) common ownership; (2) pervasive control; (3) confused intermingling of business assets; (4) thin capitalization; (5) nonobservance of corporate formalities; (6) absence of corporate records; (7) no payment of dividends; (8) insolvency at the time of the litigated transaction; (9) siphoning away of corporation's funds by dominant shareholder; (10) nonfunctioning of officers and directors; (11) use of the corporation for transactions of the dominant shareholders; and (12) use of the corporation in promoting fraud. *Attorney Gen. v. M.C.K., Inc.*, 432 Mass. 546, 736 N.E.2d 373, 380 n. 19 (2000) (citing *Pepsi-Cola*, 754 F.2d at 14-16).

[7] Courts in other jurisdictions widely follow the same rule that common ownership and management are not enough to warrant the disregard of the corporate form. *See United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (overlap in directors or officers among affiliated corporate entities is not unusual, and is widely held to be insufficient to establish alter ego liability alone); *Am. Protein Corp. v. AB Volvo*, 844 F.2d 56, 57 (2d Cir. 1988) (overlap in directors or officers among affiliated corporate entities is not unusual, and is widely held to be insufficient to establish alter ego liability alone); *Steven v. Roscoe Turner Aeronautical*, 324 F.2d 157, 161 (7th Cir. 1963) ("[w]hile stock control and common directors and officers are

conclusory, formulaic assertion that "there has existed a unity of interest in ownership between Defendants NECC, Ameridose, MSM, and Alaunus, such that any individuality and separateness between them has ceased, and each such entity is the alter ego of each other entity" and that "[a]dherence to the fiction of the separate existence of each such Defendant as an entity distinct from each other would permit an abuse of the corporate privilege, sanction fraud, and promote injustice," *id.* at ¶ 21, and refuse to hold Alaunus vicariously liable for the alleged tortious conduct of any of the co-defendants under an alter-ego theory. *See Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993) (affirming dismissal of claims against corporate defendant because naked assertion of alter ego liability was not supported by sufficient factual allegations).[8]

**c. The Complaint does not contain an adequate factual basis to distinguish the conduct of Alaunus from that of the other co-defendants since the pleading impermissibly "lumps" NECC, Ameridose, MSM and Alaunus together as one entity.**

The pleading rules have eschewed the "lumping" of defendants together. A complaint fails to meet the minimum standard of pleading under Fed.R.Civ.P. 8(a) where the complaint does not contain an adequate factual basis to distinguish the conduct of particular defendants. *See Bagheri v. Galligan*, 160 Fed. Appx. 4, 5, 2005 WL 3536555 (1st Cir. 2005) (upholding district court's dismissal of action where the original complaint did not "state clearly which defendant or defendants committed each of

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generally prerequisites for application of the instrumentality rule, yet, they are not sufficient by themselves to bring the rule into operation"); *Akzona, Inc. v. E.I. Du Pont de Nemours & Co.*, 607 F. Supp. 227, 237 (D. Del. 1984) (holding that overlapping directors was insufficient to pierce veil).

[8] *See also De Jesus v. Sears, Roebuck & Co.*, 87 F.3d 65, 70 (2d Cir. 1996) (granting 12(b)(6) motion to dismiss since complaint was "devoid of any specific facts or circumstances supporting" liability of an individual on a veil piercing theory); *In re Currency Conversion Fee Antitrust Litig.*, 265 F. Supp. 2d. 385, 426 (S.D.N.Y. 2003)("purely conclusory allegations cannot suffice to state a claim based on veil piercing or alter-ego liability, even under the liberal notice pleading standard"); *Lovely Peoples Fashion, Inc. v. Magna Fabrics, Inc.*, 95 CIV. 8450 AGS, 1996 WL 732634, *5 (S.D.N.Y. Dec. 19, 1996) (granting motion to dismiss against individual shareholders for failure to "state some basis in fact for piercing the corporate veil" where complaint's sole allegation was that shareholders "control and operate the [corporation] as their alter egos for the benefit of themselves and their families"); *Chen v. Century Buffet and Restaurant*, 2011 U.S. Dist. Lexis 43102 (D. N.J. 2011) (granting 12(b)(6) motion to dismiss under *Twombly* for failure to plead sufficient facts to support an alter ego theory of liability); *Centrifugal Air Pumps Australia v. TCS Obsolete, LLC*, 610-CV-820-ORL-31DAB, 2010 WL 3584948 at *2 (M.D. Fla. Sept. 9, 2010) (plaintiff's failure to plead facts in support of its conclusory veil piercing allegations required dismissal of individual LLC members from action); *Norfolk Southern Railway Co. v. Trinity Industries, Inc.*, 2009 WL 362437, at *8 (N.D. Tex. Feb. 13, 2009) (granting Rule 12(b)(6) motion for failure to plead sufficient facts to pierce corporate veil).

the alleged wrongful acts"); *Tolbert v. Clarke*, Civ. Action No. 10-11643, 2011 WL 797372 (D. Mass. 2011) (Zobel, J.) ("lumping" of all of the defendants together is impermissible when it cannot be reasonably inferred that all of the defendants were involved, or it is otherwise not clear to which defendant or defendants the plaintiff is referring).

Here, the Complaint impermissibly "lumps" NECC, Ameridose, MSM, and Alaunus together. Ostensibly, the Plaintiffs refer to NECC, Ameridose, MSM and Alaunus collectively as "Defendants,"[9] on the basis that Alaunus was purportedly involved in the distribution of NECC's and Ameridose's products and that they are all alter-egos of one another. *See Pl. Comp.* at ¶¶ 11 and 21. However, the Complaint offers nothing but conclusory assertions in support of such allegations. Given that the Complaint does not warrant the treatment of the corporate defendants as one entity, the Complaint impermissibly "lumps" Alaunus together with the other co-defendants. Therefore, all counts of the Complaint should be dismissed as to Alaunus under *Twombly-Iqbal* because the allegations in the pleading fail to give adequate notice to Alaunus as to what it did wrong and therefore falls short of the pleading standards of Rule 8(a). *See Bagheri*, 160 Fed. Appx. at 5; *Tolbert*, 2011 WL 797372 (D. Mass. 2011) (Zobel, J.).[10] *See also Gomez v. Pfizer, Inc.*, 675 F. Supp.2d 1159 (S.D. Fla. Dec. 21, 2009) (dismissing negligence claim against manufacturer in product liability action due to failure to plead individualized allegations against defendants).

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[9] For example, Plaintiff alleges that "*Defendants* were aware, or should have been aware, that the recalled vials of methylprednisolone acetate were at significantly increased risk of contamination . . ." and that "*Defendants* failed to stop production and sale of the vials . . ." *Pl. Compl.* at ¶¶ 52 -53 (emphasis applied).

[10] *See also Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2d Cir.2001) ("By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff]'s complaint failed to satisfy [the] minimum standard" of pleading under Fed.R.Civ.P. 8(a)"); *Goren v. New Vision Intern., Inc.*, 156 F.3d 721, 730 (7th Cir.1998) (affirming dismissal of complaint where complaint treated defendants as one, "lumping" them together); *Vanzandt v. OK Dep't Human Serv's.,* 276 Fed. Appx. 843 (10th Cir. 2008) ("To carry their burden, plaintiffs under the *Twombly* standard must do more than generally use the collective term 'defendants.' . . . This is because the purposes of plausibility, notice, and gatekeeping are best served by requiring plaintiffs to directly link an actual individual with the alleged improper conduct"); *Medina v. Bauer*, 2004 WL 136636, 6 (S.D.N.Y. Jan. 27, 2004) ("by lumping all the defendants together and failing to distinguish their conduct, plaintiff's Complaint fails to satisfy the requirements of Rule 8 . . . the allegations fail to give adequate notice to these defendants as to what they did wrong"); *Pietrangelo v. NUI Corp.*, 2005 WL 1703200, * 10 (D. N.J. 2005) (Brown, J.) (ruling that "lumping together" of defendants "fails to put the various defendants on notice of the allegations against them" as required by Rule 8(a) and dismissing complaint because it failed to mention several defendants individually in any of the allegations, instead, referring to all of the defendants collectively as "Defendants" throughout).

**2. The Complaint does not contain sufficient allegations to show that Alaunus is liable for the conduct alleged.**

Turning to the causes of action asserted in the Complaint, the Plaintiff woefully fails to show that Alaunus is liable for any illegal conduct under Indiana law.

**a. The Plaintiffs' Claims Are Governed by Indiana Law.**

Applying the choice of law rules articulated under Massachusetts law,[11] this Court should apply Indiana's substantive product liability, survival, and wrongful death laws to the question as to whether Alaunus may be held liable to the Plaintiffs.

As a threshold matter, there is a true conflict of law between the substantive product liability, survival, and wrongful death laws of Massachusetts and Indiana. While the law in Massachusetts permits product liability actions based on theories of common law negligence, breach of express and implied warranty, and other theories, the law in Indiana does not. The Indiana Products Liability Act governs ***all*** product liability actions brought by a user or consumer[12] against a manufacturer or seller[13] for physical harm caused by a product, ***regardless of the substantive legal theory of theories upon which the action has been brought***. Ind. Code § 34-20-1-1 (emphasis added); *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 976 (Ind. 2002). *See Conley v. Lift-All Co.*, 2005 U.S. Dist. LEXIS 15468, 12-13 (S.D. Ind. July 25, 2005) ("[t]he IPLA effectively supplants [] common law claims because all [] claims are brought by a user or consumer against a manufacturer for physical harm caused by a

[11] Whereas choice of law is a substantive rule of law, the district court normally follows the choice of law rules of the state in which the district court sits. *Klaxon Co. v. Stentor Elec. Mfg.*, 313 U.S. 487, 496–97 (1941). When a diversity action is transferred pursuant to 28 U.S.C. § 1407, the transferee court is obligated to apply the state substantive law as determined by the choice of law analysis required by the state in which the action was originally filed. *See Ferens v. John Deere Co.*, 494 U.S. 516, 524-32 (1990) (evaluating applicable law after change of venue under 28 U.S.C. § 1404(a) and holding that transferee forum was required to apply law of transferor court, regardless of which party initiated transfer). Since this action was directly filed in this Court, Massachusetts' choice of law rules apply.

[12] The IPLA defines a user or consumer, in relevant part, as "a purchaser, or any individual who uses or consumes the product." Ind. Code § 34-6-2-29.

[13] A manufacturer is defined as "a person or an entity that designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer." Ind. Code § 34-6-2-77. A seller is defined as "a person engaged in the business of selling or leasing a product for resale, use, or consumption." Ind. Code § 34-6-2-136.

product. Plaintiff's common law claims will therefore be treated as merged into the IPLA claims"); *Campbell v. Supervalu, Inc.*, 565 F.Supp.2d 969, 976 (N.D. Ind. 2008) (holding that a plaintiff's "attempt to cast [defendant]'s action as one of 'simple negligence,' and therefore somehow falling outside the reach of the Indiana Product Liability Act, clearly fails").[14]

To the extent that Indiana law applies, Plaintiff's common law claims of negligence (Count I) and negligent infliction of emotional distress (Count II) are pre-empted or subsumed by the IPLA as a matter of law. *See American Intern. Ins. Co. v. Gastite*, 2009 WL 1383277, *2 (S.D. Ind. 2009); *Ganahl v. Stryker Corp.*, No. 1:10-cv-1518-JMS-TAB, 2011 WL 693331, at *3 (S.D. Ind. Feb. 15, 2011) (plaintiff's common law negligence and strict product liability claims arising out of personal injuries suffered from use of medical device were subsumed by IPLA); *McGookin v. Guidant Corp.*, 942 N.E.2d 831 (Ind. App. January 21, 2011 (claim for negligent infliction of emotional distress merged into a single cause of action under the IPLA).

Additionally, Plaintiff's claims for breach of express and implied warranties (Count III) are also subsumed by the IPLA to the extent that Indiana law applies. "The Indiana Court of Appeals and several federal district courts sitting in Indiana have all held that tort-based breach of warranty claims have been subsumed into the [I]PLA." *Hathaway v. Cintas Corporate Services*, No. 1:10 CV 195, 2012 WL 4857828, at *2 (N.D. Ind. Oct. 11, 2012) (Moody, J.).[15] Because Plaintiff's claims for breach of express and implied warranties are all based in tort for bodily injury caused by the use of the MPA product, the IPLA provides the exclusive remedy, thereby barring any common law cause of action for breach of warranty. *Id.*, at *3 (holding that plaintiff's common law claims for breach of express and implied warranties arising out of severe burn injuries from spark created by machine used

[14] *See also Cincinnati Ins. Cos v. Hamilton Beach/Proctor-Silex, Inc.*, 2006 U.S. Dist. LEXIS 9807, at *2 (N.D. Ind. Feb. 7, 2006); *Ryan v. Philip Morris USA, Inc.*, 2006 U.S. Dist. LEXIS 9077, at *9 (N.D. Ind. Feb. 22, 2006).

[15] *See also Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011); *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor–Silex, Inc.*, No. 4:05 CV 49, 2006 WL 299064, at *3 (N.D. Ind. Feb.7, 2006); *N.H. Ins. Co. v. Farmer Boy AG, Inc.*, No. IP 98–0031–C–T/G, 2000 WL 33125128, at *3 (S.D. Ind. Dec.19, 2000); and, *Condon v. Carl J. Reinke & Sons, Inc.*, 575 N.E.2d 17, 18 (Ind.Ct.App.1991).

to cut metal were subsumed under IPLA).[16]

Moreover, the common law battery, loss of consortium, and wrongful death claims are supplanted by the IPLA if Indiana law applies. Whereas the legislature intended that the IPLA provide the exclusive remedy for "physical harm," which is defined as "bodily injury, death, loss of services . . . ," Ind. Code sec. 34-6-2-105, ***regardless of the substantive legal theory of theories upon which the action has been brought***, the Indiana courts have held that the IPLA supplants any claim, whether based on negligent acts or omissions or intentional conduct and regardless of the extent of the injury asserted, arising out of physical harm from the use of a product. *See Ryan v. Philip Morris USA, Inc.*, No. 1:05CV162, 2006 WL 449207 (N.D. Ind. 2006) (ruling that plaintiff's fraud claim falls within purview of IPLA); *McGookin v. Guidant Corp.*, 942 N.E.2d 831 (Ind. App. January 21, 2011 (observing that trial court correctly merged all claims, including claims for actual and constructive fraud, into a single cause of action under the IPLA).

Furthermore, any and all claims for personal injuries that accrued in favor of Mr. Stout did not survive his death to the extent that Indiana law applies. Under Massachusetts law, claims for personal injuries such as those at issue in this case did not survive the death of the injured person at common law, *Connors v. Newton Natl. Bank*, 336 Mass. 649 (1964), but do survive under Massachusetts' Survival Statute, M.G.L. c. 228, s. 1, which provides that "in addition to the actions which survive by the common law, the following shall survive: . . . (2) Actions of tort (a) for assault, battery, imprisonment or other *damage to the person . . .*" *Rendek v. Sheriff of Bristol County*, 440 Mass. 1017 (2003) (emphasis supplied). *See Norton v. Sewall*, 106 Mass. 143 (1870) (ruling that the words "damage to the person" as used in the survival statute include "every damage of a physical character" and holding that an action of negligence against an apothecary for selling a deadly poison as and for a

[16] *See also Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011) (express warranty claim based in tort supplanted by IPLA); *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 153 (Ind. 2005) ("Indiana law under the Products Liability Act and under general negligence law is that damage from a defective product or service may be recoverable under a tort theory if the defect causes personal injury or damage to other property, but contract law governs damage to the product or service itself and purely economic loss arising from the failure of the product or service to perform as expected").

harmless medicine, the taking of which caused the decedent's death survived). On the other hand, any product liability claims that accrued in favor of Mr. Stout did not survive his death to the extent that Indiana law applies because Plaintiff claims that Mr. Stout died from personal injuries resulting from his use of an MPA product. *See* Ind. Code § 34-9-3-1(a)(6) (providing that if an individual who has a personal injury claim or cause of action dies, the claim or cause of action does not survive-unless the individual dies from causes other than those personal injuries); *Technisand, Inc. v. Melton*, 898 NE 2d 303, 306 (Ind. 2008) (holding that, pursuant to Indiana's Survival Act (Ind. Code § 34-9-3-1(a)(6)), the decedent's product liability claim against defendant terminated at her death and the only claim that survived was the plaintiff's claim under Indiana's Wrongful Death Act where the injuries forming the basis for the substantive tort claim, that of products liability, caused the decedent's death). In short, there is a true conflict of laws because, on the one hand, Plaintiffs may bring actions for negligence, breach of express and implied warranties, and other common law causes of action if Massachusetts law applies and, on the other hand, the exclusive cause of action available to the Plaintiff is a claim under Indiana's General Wrongful Death Act ("IWDA") if Indiana law applies.

There is no question that the substantive product liability and survival laws of Indiana governs this dispute. Under Massachusetts' choice-of-law rules, tort claims are governed by the law of the state in which the injury occurred, unless another state has a more significant relationship *to the underlying cause of action*. *Bergin v. Dartmouth Pharm., Inc.*, 326 F. Supp. 2d 179, 183 (D. Mass. 2004), citing *Dunfey v. Roger Williams Univ.*, 824 F. Supp.18, 21 (D. Mass. 1993). The place where the injury occurred is Indiana because that is where Mr. Stout received his medical treatment and was allegedly exposed to contaminated MPA. *See Cohen v. McDonnell Douglas Corp.*, 389 Mass. 327, 334 (1983) (injury occurs for purposes of choice of law analysis "where the last event necessary to make an actor liable for an alleged tort takes place").

Massachusetts does not have a more significant relationship to the underlying product liability claims. The fact that Plaintiffs chose to file suit in the Commonwealth or that Massachusetts was

selected as the forum for this MDL does not affect a forum change for choice of law purposes. *See*, e.g., *In re Guidant Corp. Implantable Defibrillators Prods. Liability Litigation*, 489 F. Supp. 2d 932, 935 (D. Minn. 2007) (explaining that absent a stipulation between the parties, the filing of a master complaint does not make the MDL court the controlling forum for choice of law purposes or alter which state's laws govern plaintiffs' claims); *In re Propulsid Prod. Liab. Litig.*, 208 F.R.D. 133, 141-42 (E.D. La. 2002) (master complaint does not effect a forum change for choice of law purposes). While Massachusetts has an interest in regulating businesses that operate within its borders, it is significant that none of the allegedly contaminated lots of MPA were distributed in Massachusetts, there are no reported MPA-related meningitis cases in Massachusetts, and there are no claimants in this MDL who are residents of Massachusetts. Under these circumstances, Massachusetts' interest in regulating business' to deter the distribution of unsafe products within its borders is outweighed by the interests of the states where Plaintiff and each of the individual members of the putative class reside in providing their residents with pharmaceutical products by creating more predictable standards of care for drug companies that would encourage the drug companies to market their products in those states. *See Rowe v. Hoffmann-La Roche Inc.*, 917 A.2d 767 (N.J. 2007) (affirming trial court's decision that Michigan substantive law applied in products liability action by resident of Michigan who sustained an alleged injury in Michigan against New Jersey manufacturer and that the defendant-manufacturer was therefore immune from liability under Michigan statute because, after comparing the different state interests under New Jersey's governmental interest choice of law rules, Michigan's interest in providing its citizens with affordable medications prevailed over New Jersey's interest in regulating its manufacturers).

**b. <u>The Complaint Fails to State a Viable Claim under the IPLA.</u>**

When Indiana Code sections 34-20-1-1 and 34-20-2-1 are read together, there are five (5) unmistakable threshold requirements for IPLA liability: (i) a claimant who is a user or consumer and is also in the class of persons that the seller should reasonably foresee as being subject to the harm

caused; (ii) a defendant that is a manufacturer or a seller engaged in the business of selling a product; (iii) physical harm caused by a product; (iv) a product that is in a defective condition unreasonably dangerous to a user or consumer or to his property; and (v) a product that reached the user or consumer without substantial alteration in its condition. *See* Ind. Code 34-20-1-1; 34-20-1-2. *Bourne v. Marty Gilman, Inc.*, 452 F.3d 632, 635 (7th Cir.2006); *Williams v. REP Corp*., 302 F.3d 660 (7th Cir. 2002). "[A] plaintiff can satisfy the second element-that the product was defective-by showing one of the following: a design defect, a manufacturing defect, or a failure to warn." *Ritchie v. Glidden Co.*, 242 F.3d 713, 720 (7th Cir.2001); *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind.Ct.App.1997). Plaintiff's Complaint falls short of satisfying any of these elements.

**i. Alaunus is Not a "Manufacturer" or "Seller" of MPA.**

The Complaint does not sufficiently allege that Defendant Alaunus is a "manufacturer" or a "seller" of MPA. Putting aside the allegations pertaining to the alter-ego claim, the only allegation that pertains to Alaunus' alleged involvement in the manufacture and sale of MPA is the statement in paragraph 11 of the Complaint that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose." For the reasons set forth above, that statement is merely an unsupported, conclusory assertion masquerading as a factual allegation which should not be deemed as true on a 12(b)(6) motion. Because the Plaintiff has failed to *show* that Alaunus is a "manufacturer" or "seller," the Complaint does not state a plausible claim against Alaunus under the IPLA. *See Williams v. REP Corp.*, 302 F.3d 660, 666 (7th Cir. 2002) (defendant that did not sell, lease or otherwise put into the stream of commerce the machine that caused plaintiff's injury could not be held liable under the IPLA); *Chappey v. Ineos USA L.L.C.*, No. 2:08-CV-271, 2009 U.S. Dist. LEXIS 24807 (N.D. Ind. Mar. 23, 2009) (dismissing IPLA claim concluding that the plaintiff had "not alleged that [defendant] was a manufacturer or a seller of any product" and that she likewise had "failed to specifically identify a product").

**ii. Product Identification/ Causation**

Like Massachusetts law, Indiana law requires a plaintiff to identify the defendant as the manufacturer or seller of a product in order to state a claim under the IPLA. *See Schork v. Baxter Healthcare Corp.*, No. 4:10-cv-00005-RLY-WGH, 2011 WL 4402602 (S.D. Ind. Sept. 22, 2011); *Mathers v. Midland-Ross Corp.*, 532 N.E.2d 46, 48-49 (Mass. 1989) (stating that Massachusetts law requires that a plaintiff suing a manufacturer in a product-liability action be able to prove that his or her injury can be traced to that specific manufacturer); *Carrier v. Riddell, Inc.*, 721 F.2d 867, 869-870 (1st Cir.1983) (applying Massachusetts law) (same).

The Complaint does not plead any factual allegations whatsoever showing that Alaunus manufactured or sold any MPA product and that Plaintiffs were injured by that product. None of the allegations in the Complaint that relate to the identification of the manufacturer and distributor, including the entity that recalled the MPA product and the entity that produced the lot numbers of the allegedly contaminated MPA product, point to Alaunus. The pleading is bereft of any other allegations which might identify *Alaunus* as the manufacturer or distributor of the MPA product that was used to treat Mr. Stout such as the name of the manufacturer or distributor listed on the injection vials that were allegedly used to treat Mr. Stout, the trademark or logo depicted on the labeling affixed to such injection vials, whether the product provided to the Plaintiffs was brand name or generic, the volume of the injection vials provided to the Plaintiffs, or whether the Plaintiffs received injections of preservative free formula or not. Given that there are no ***factual allegations*** in the Complaint that supports the Plaintiff's statement that the product that allegedly injured Mr. Stout was distributed by Alaunus, dismissal is appropriate under *Twombly-Iqbal* because it permits nothing more than a mere *possibility* that Mr. Stout was harmed by a product that was allegedly manufactured or distributed by Alaunus. *See Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. Appx. 495 (6th Cir. Aug. 23, 2011) (affirming dismissal for failure to state a claim because Massachusetts law requires that a plaintiff suing a manufacturer in a product-liability action be able to prove that his or her injury can be

traced to that specific manufacturer and the factual allegations in the complaint only permitted the Court to infer the possibility that the plaintiff received infusions of the name-brand drug, Aredia, manufactured by Novartis, as opposed to the generic equivalent manufactured by some other manufacturer).[17] Significantly, MDL Courts have not hesitated to dismiss actions where the plaintiffs' complaints failed to allege sufficient facts to show that the defendant was the manufacturer or distributor of the alleged defective product that caused injury to the plaintiffs. *See In Re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, E.D.KY. Civ. No. 11-MD-2226 (July 31, 2012); *In re Fosamax Products Liability Litigation*, S.D.N.Y. Civ. No. 06-MD-1789, 2010 WL 1654156 (April 9, 2010).

**iii. Defect**

In addition, the Complaint fails to state an IPLA claim because it does not sufficiently allege that the MPA product that was allegedly used or consumed by Mr. Stout was affected by a manufacturing defect or that the product was otherwise defective by virtue of its design or inadequate warnings.

As an initial matter, the allegation that Mr. Stout began to experience "symptoms of meningitis" a month after his second treatment with an MPA product, *Pl. Compl.* at ¶ 58, does not give rise to an inference that the MPA product was manufactured by any of the defendants. The statement that Mr. Stout began to experience "symptoms of meningitis" is conclusory because the opinion as to whether he was in fact suffering from meningitis can only be made by a qualified medical professional and the Complaint does not specify what symptoms were experienced by Mr. Stout that would form

[17] *See also Peterson v. Breg*, 2010 U.S. Dist. Lexis 48985 (D. Ariz. April 29, 2010) (dismissing complaint that failed to identify which manufacturers' products were actually used despite initially naming defendant as manufacturer of pain pump used in surgery); *Johnson v. Moog, Inc.*, 2011 WL 719600 (E.D. Tex. Feb. 22, 2011) (all claims in medical device case dismissed because the pleading asserted only that unknown "defendants" committed actions and failed to state sufficient facts to identify defective product); *Henderson v. Sun Pharmaceuticals Industries, Ltd.*, 809 F. Supp.2d 1373 (N.D. Ga. Aug. 22, 2011) (all claims dismissed due, in relevant part, to failure to allege sufficient factual allegations to identify the defendant that manufactured the product); *Singleton v. Eli Lilly Co.*, 2011 WL 2621067 (E.D. Cal. June 29, 2011) (all claims in prescription drug case dismissed due to failure to allege sufficient factual allegations to identify the product's manufacturer); *McFarland v. APP Pharmaceuticals, LLC*, 2011 WL 2413797 (W.D. Wash. June 13, 2011) (all claims in prescription drug/medical device case dismissed due to failure to identify the product's manufacturer).

the basis of any such medical opinion. *See Dartmouth Review*, 889 F.2d at 16 (the court "need not credit [g]auzy generalities, unsupported conclusions, subjective characterizations, and problematic suppositions"). In any event, the adverse reaction of spinal meningitis is consistent with the known adverse reactions associated with the use of ***non-contaminated, brand-named*** methylprednisolone acetate that was ***not*** manufactured by NECC. The FDA-approved labeling[18] for brand-named injectable methylprednisolone acetate contains a warning that states:

> "Persons who are on corticosteroids are more susceptible to infections than are healthy individuals . . . *Infections with any pathogen (viral, fungal, protozoan, or helminthic), in any location of the body may be associated with the use of corticosteroids alone* . . . These infections may be mild, but can be severe and at times fatal . . . Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control drug reactions . . . Latent disease may be activated or there may be an exacerbation of intercurrent infections due to pathogens. . . " (emphasis supplied).[19]

In addition to headaches, muscle pain, nausea, and other flu-like symptoms, meningitis has been reported as an adverse reaction associated with the use of *brand-named* methylprednisolone acetate that is manufactured by a third party and that is not contaminated with any fungal agent.[20] While the Complaint asserts that the MPA product that was used to treat Mr. Stout was from one of the NECC lots that were allegedly contaminated with a fungal agent, there are no facts (as opposed to conclusory assertions) plead in the Complaint to support the inference that the MPA product was in fact from one of those lots. Thus, the Complaint does not establish that Mr. Stout's MPA product was manufactured

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[18] This Court may consider the contents of the FDA-approved labeling for methylprednisolone acetate on a motion to dismiss under Rule 12(b)(6) without converting the motion to one for summary judgment because it is an official public record susceptible to judicial notice under Federal Rule of Evidence 201 and/or a document central to the Plaintiff' claim. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1998); *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1223 n.2 (9th Cir. 2004) ("We may take judicial notice of a record of a state agency not subject to reasonable dispute"); *O'Toole v. Northrop Grumman Corp.*, 499 F.3d 1218, 1225 (10th Cir. 2007) ("It is not uncommon for courts to take judicial notice of factual information found on the world wide web"); *New Mexico ex rel. Richardson v. Bureau of Land Management*, 563 F.3d 683 (10th Cir. April 28, 2009) (No. 06-2352, 06-2353, 06-2354) (taking judicial notice of releases which were referred to on the websites of two federal agencies because it was not subject to reasonable factual dispute and is capable of determination using sources whose accuracy cannot reasonably be questioned).

[19] *See* U.S. FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program, Safety Information - Depo-Medrol/S-085 Label (methylprednisolone acetate injectable suspension, USP), available at <http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/011757s085s086lbl.pdf> (accessed Jan. 3, 2013).

[20] *See id.*

by NECC as opposed to some other third party manufacturer.

In sum, the adverse reaction that was allegedly experienced by Mr. Stout is wholly consistent with *side effects* from the *name-brand* version of *non-contaminated* methylprednisolone acetate which, according to the FDA label, was not manufactured or distributed by NECC, Ameridose, or Alaunus. Additionally, there are no factual allegations (as opposed to conclusory assertions) showing that contaminated product was in fact distributed to Mr. Stout's healthcare provider, that such product was in fact provided to him, or otherwise identifying the manufacturer or distributor of the MPA product that was allegedly consumed by him. Therefore, it is not plausible to suggest that the injections received by the Plaintiff was contaminated – or that his symptoms were caused by fungal contamination – merely because Mr. Stout allegedly experienced an adverse reaction to his steroid injections. *See Smith v. Michigan Beverage Co.*, 495 F.2d 754, 757 (7th Cir. 1974) ("just as it is the general rule that the mere fact of injury will not create an inference of negligence, the mere fact of the accident cannot create an inference of a defect in a products case"). Thus, the Complaint should be dismissed for failure to allege a plausible manufacturing defect claim.

Nor does the Complaint plead a viable design or warning defect claim. While the pleading states that "the product warnings in effect when Plaintiff's decedent and class members were injected with the recalled methylprednisolone acetate steroids were both substantially and graphically wholly inadequate to alert prescribing physicians and patients[21] of the actual risks associated with these drugs, which risks were known, or should have been known, to Defendants," *Pl. Compl.*, at ¶55, there are no factual allegations in the Complaint explaining *how* the warnings and instructions were inadequate or *how* the design of the MPA product was defective. Given that the Complaint does not provide the Defendants with adequate notice of the factual basis of Plaintiffs' warning and design defect claims,

[21] Any claim that the Defendant breached a duty to warn Mr. Stout, as opposed to his physician, fails as a matter of law under Indiana's Learned Intermediary Doctrine. *See Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548-49 (Ind. Ct. App. 1979) (since drugs are available only by prescription, a manufacturer's duty to warn extends only to the medical profession, and not the ultimate users); *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987) (manufacturer of catheter had no duty to warn users of the catheter other than the operating surgeon who installed the catheter); *Menges v. DePuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999).

the Complaint fails to state a plausible warning or design defect claim under the IPLA. *See Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. Appx. 597 (11th Cir. July 29, 2008) (warning defect claims dismissed due to failure to plead facts concerning how the warning to the prescribing physician was inadequate); *Ivory v. Pfizer Inc.*, 2009 WL 3230611 (W.D. La. Sept. 30, 2009) (design defect claim against drug manufacturer dismissed due to failure to plead facts establishing a feasible alternative design).[22]

**c. The Claims for Negligent Infliction of Emotional Distress Should Be Dismissed Because Mr. Stout's Claim Did Not Survive His Death and Mrs. Stout Did Not Suffer "Physical Harm."**

The claims for negligent infliction of emotional distress should be dismissed for several reasons. As established above, any and all claims by Julia Stout and the decedent's estate for negligent infliction of emotional distress are subsumed by the IPLA. Mr. Stout's claim for emotional distress under the IPLA terminated upon his death. Mrs. Stout's claim for emotional distress fails because the Complaint does not allege that she was exposed to any contaminated MPA product and emotional distress does not constitute "physical harm" within the meaning of the IPLA. *See Doerner v. Swisher Intern., Inc.*, 272 F.3d 928, 931 (7th Cir. 2001) (affirming dismissal of widow's claim for emotional distress damages under the IPLA holding that "the plain language of the IPLA requires that [plaintiff] establish that she suffered a 'physical harm' caused by a product regardless whether Indiana common law would have required her to do so" and that "'mental distress' does not qualify as a 'physical harm' under the IPLA.").

[22] *See also Reed v. Pfizer Inc.*, 2012 WL 859729 (E.D.N.Y. March 14, 2012) (warning claims dismissed due to failure to plead what the warning was or how it was inadequate, particularly since the precise risk was in fact warned of, and design claims dismissed due to failure to plead any alternative design); *Lewis v. Abbott Laboratories*, 2009 WL 2231701 (S.D.N.Y. July 24, 2009) (design claim dismissed due to failure to plead facts establishing a feasible alternative design and warning claims dismissed due to failure to plead inadequate warnings to doctors under the learned intermediary rule); *Heck v. American Medical Systems, Inc.*, 2008 WL 1990710 (D. Md. April 30, 2008) (all product liability claims dismissed due to unsubstantiated labels and legal conclusions, as well as failure to distinguish between manufacturing, design, and warning defects); *Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp.2d 787 (S.D. Ohio July 23, 2009) (design and manufacturing claims against drug manufacturer dismissed due to formulaic pleadings of defect and causation); *Nimtz v. Cepin*, 2011 WL 831182 (S.D. Cal. Mar. 3, 2011), dismissed with prejudice, 2011 WL 2160181 (S.D. Cal. June 1, 2011) (all manufacturing, design, and warning claims dismissed due to failure to plead more than "legal conclusions" concerning the elements of the causes of action since there was no allegations in complaint stating how the product was inadequately designed or manufactured, and complaint failed to identify which danger was not warned against).

**d. The Claim for Breach of Express Warranty Should Be Dismissed Because the Complaint Does Not Show that Alaunus Made Any Affirmation of Fact or that Plaintiff Relied on Any Such Warranty.**

The express warranty claim should be dismissed because it is subsumed by the IPLA and terminated upon Mr. Stout's death. Additionally, the breach of express warranty claim should be dismissed due to the failure to specify the precise nature of any affirmation of fact which could form the basis of an express warranty. The Plaintiff's Complaint baldly asserts that "included with the steroid injection at the time of purchase were express and implied warranties made by Defendants affirming that the product was dependable, reliable, free from defects, of merchantable quality, of fair use and quality, sterile, and fit for its intended purpose." *Pl. Compl.*, at ¶ 92. Given that the Complaint does not plead any facts, as opposed to conclusory assertions, regarding the specific affirmation of fact or promise that was made by Alaunus to Mr. Stout or otherwise identify any of the specific advertisements or promotional materials which were supposedly sent by Alaunus to the Plaintiff, the express warranty claim should be dismissed for failure to state a claim pursuant to *Twombly* and *Iqbal*. *See Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194, 206 (D. Mass. 2000) (dismissal of express warranty claim appropriate where plaintiff claimed that the defendant extended an express warranty to the decedent through its "advertising, marketing and other efforts," but offered no specific affirmation of fact or promise, nor any particular description, sample or model that might give rise to such a warranty); *Varney v. R.J. Reynolds Tobacco Co.*, 118 F.Supp.2d 63, 70 (D.Mass.2000) (dismissal appropriate where plaintiff did not plead "the existence of anything remotely resembling an express warranty").

**e. The Claims for Breach of Express and Implied Warranty of Fitness for Particular Purpose Should Be Dismissed for Lack of Privity.**

In addition to being subsumed by the IPLA and terminating upon Mr. Stout's death, the claims for breach of express warranty and breach of the implied warranty of fitness for particular purpose should be dismissed because the Complaint does not show the existence of privity between Mr. Stout

and Alaunus.

Under Indiana law, vertical privity is required for claims of breach of express warranty and breach of implied warranty of fitness for a particular purpose. *See Davidson v. John Deere & Co.*, 644 F. Supp. 707, 713 (N.D. Ind. 1986) (plaintiff did not have a claim for breach of express warranty because "[p]rivity has not been abrogated as a requirement in contract actions for breach of warranty"); *Hunt v. Unknown Chem. Mfr. No. One*, No. IP 02-389-C, 2003 U.S. Dist. 20138, at *34-35 (S.D. Ind. Nov. 5, 2003) (stating that "a plaintiff bringing a breach of implied warranty of fitness for a particular purpose claim under IND. CODE § 26-1-2-315 must show privity of contract"); *Atkinson v. P&G-Clairol, Inc*., 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011) (contract-based claim for breach of implied warranty of fitness for particular purpose dismissed because plaintiff did not state from whom she bought the product or that she entered into any type of bargain or purchase agreement with defendant). "Simply put, vertical privity exists only between immediate links in a distribution chain. A buyer in the same chain who did not purchase directly from a seller is 'remote' as to that seller." *Hyundai Motor Am., Inc. v. Goodin*, 822 N.E.2d 947, 952 (Ind. 2005). Vertical privity "becomes an issue when a purchaser files a breach of warranty action against a vendor in the purchaser's distribution chain who is not the purchaser's immediate seller." *Id.*

Here, the Complaint alleges that Mr. Stout received the MPA product from his medical provider, as opposed to purchasing the product directly from any of the defendants. Accordingly, the claims for breach of express warranty and implied warranty of fitness for a particular purpose should be dismissed for lack of privity. *See Goodin*, 822 N.E.2d at 952; *Davidson*, 644 F. Supp. at 713; *Atkinson*, 813 F. Supp. 2d at 1025.

**f. Count IV (Battery) Should Be Dismissed Because Plaintiff Does Not Allege that Mr. Stout Did Not Consent to the Use of the MPA Product.**

As established above, any claim for battery that Mr. Stout may have had is supplanted by the IPLA and terminated upon his death under Indiana's Survival Act. Additionally, the Complaint fails to

state a claim for battery against Alaunus because the pleading does not allege that Mr. Stout did not consent to treatment by injection with MPA. As this Court stated in *Moore v. Eli Lilly and Co.*, 626 F.Supp. 365 (D. Mass. 1986) (Wolf, D.J.), a cause of action for battery may only be maintained where there is a *lack of any consent* by the patient to the treatment, *In the Matter of Spring*, 380 Mass. 629, 638 (1980), *Mink v. University of Chicago*, 460 F.Supp. 713, 717 (N.D.Ill.1978), while he must rely on a negligence action alleging a *lack of informed consent* if the patient was aware that he was given some form of drug but claims that he was not informed about a medication's inherent dangers, *Mink*, 460 F.Supp. at 717, *Halley v. Birbiglia*, 390 Mass. 540 (1983). Thus, the Complaint fails to state a plausible claim for battery because it does not allege facts which, if proven, would establish a *lack of consent*, rather than a *lack of informed consent* since Plaintiff does not allege that Mr. Stout did not consent to treatment with the MPA product. *See Moore*, 626 F.Supp. at 368 (ruling, in pharmaceutical drug case, that plaintiffs' battery claim against manufacturer was futile where complaint did not allege that lead plaintiff did not consent to take drug at issue).

**g. Count V (Failure to Warn) Should Be Dismissed Because It is Simply a Recast Version of the Failed Negligence Claim.**

The failure to warn claim should be dismissed as to Alaunus for several reasons. Count V of the Complaint does not list Alaunus as a defendant subject to that count. Count V is duplicative of Count I in that they are both based, in relevant part, on the assertion that Mr. Stout suffered an injury from his use of an MPA product because the defendants failed to exercise reasonable care in warning consumers that the product was allegedly contaminated with a fungal agent. *See Pl. Compl.* ¶¶ 82 and 107 - 110. There is no separate cause of action for failure to warn because it is a *type of defect* that may form the basis of a product liability claim, not an *independent tort*. *See Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (Ind. 1981) (failure to warn claims are based on a theory of negligence and covered by the IPLA); *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 921 (Mass. 1998) ("evidence of failure adequately to test a product is relevant to claims of design, manufacturing, or

warning defects, but does not furnish a separate, independent basis for liability"). Consequently, Count V should be dismissed because it is merely a recast version of the failed common law negligence claim which is subsumed by the IPLA and terminated upon the death of Mr. Stout.

**h. Count VI (Loss of Consortium) Should Be Dismissed Because the Claim is Derived From the Failed Product Liability Claims Against Alaunus.**

A cause of action is derivative if it may be brought only where a separate, related claim is actionable. *Durham v. U-Haul Int'l*, 745 N.E.2d 755, 764 (Ind. 2001). The derivative claimant must prove all the elements of the related tort in order to recover. *Mayhue v. Sparkman*, 653 N.E.2d 1384, 1386 (Ind.1995). A spouses' claim for loss of consortium is derivative, Ind.Code § 34-18-2-22, because it "derives its viability from the validity of the claim of the injured spouse against the wrongdoer." *Nelson v. Denkins*, 598 N.E.2d 558, 563 (Ind. Ct. App.1992). Given that the Complaint fails to state a claim on behalf of Mr. Stout's estate against Alaunus, the loss of consortium claim by Mrs. Stout fails as a matter of law and should be dismissed since it is derivative of her belated husband's failed claims against Alaunus.

**i. Count VII (Limited Fund Constructive Trust) Should Be Dismissed Because It is a Remedy, Not a Cause of Action, and There is No Basis to Impose Liability Against Alaunus.**

A constructive trust is a remedy, not a cause of action. *See Barry v. Covich*, 332 Mass. 338, 342 (1955) (ruling that a constructive trust may be said to be a device employed in equity in order to avoid the unjust enrichment of one party at the expense of the other); *Chosnek v. Rolley*, 668 N.E.2d 202, 211 (Ind. Ct. App. 1997) ("[a] constructive trust…is more in the nature of an equitable remedy than an independent cause of action"). Consequently, the "limited fund constructive trust" remedy is only available to the Plaintiff if she succeeds on the merits of her claims for liability against the Defendants. Given that the Plaintiff has not established fraud, breach of fiduciary duty, or other misconduct by Alaunus, no limited fund constructive trust may be imposed as to it. *See Barry v. Covich*, 332 Mass. 338, 342 (1955) (no constructive trust shall be imposed absent fraud, breach of a

fiduciary duty or other misconduct); *Collins v. Guggenheim*, 417 Mass. 615, 617–618 (1994) (same).

**j. Count VIII (Wrongful Death) Should Be Dismissed Because the Complaint Does Not Show that Mr. Stout's Death Was Caused by An Act or Omission of Alaunus.**

To recover for wrongful death, the Plaintiff must allege and prove that the death of Mr. Stout was caused by a "wrongful" act or omission by Alaunus. *See* Ind. Code § 34-23-1-1 (providing that a personal representative may bring an action for wrongful death "when the death of one is caused by the wrongful act or omission of another . . ."). As established above, the Complaint does not plead sufficient facts to show that Alaunus is the "manufacturer" or "seller" of any product, that Alaunus committed any wrongful act, or that Mr. Stout's injuries were caused by a defect in a product that is attributable to Alaunus. Given that the Complaint does not plead sufficient facts to *show* that the death of Mr. Stout was caused by any negligent acts or omissions or breach of warranty by Alaunus, Plaintiff's claim under the IWDA fails.[23]

**k. The Claim for Class Certification Should Be Dismissed for Lack of Predominance.**

Alaunus briefed an argument seeking dismissal under Rule 12(b)(6) of a national class action claim that was asserted by the plaintiff in a related action pending in this multi-district litigation. *See McDow, et. al. v. New England Compounding Pharmacy, Inc.*, Civ. Action No. 12-12112-FDS, Alaunus' Reply Brief in Support of Its Motion to Dismiss, pp. 9 – 13, [Document No. 184, Feb. 8, 2013]. The class claim asserted in this action is similar to the class claim asserted in *McDow* and should be dismissed for the same reasons asserted in Alaunus' Reply Brief that was filed in *McDow*. For the sake of economy, Alaunus incorporates by reference the argument asserted on pages 9 -13 of its Reply Brief that was filed in *McDow* as if it were fully made in this brief.

[23] The same result follows if this Court were to apply Massachusetts' Wrongful Death Statute. *See* M.G.L. c. 229, § 2 (providing that a personal representative may bring an action for wrongful death where a person's death is caused, in relevant part, by the defendant's negligence, or willful, wanton or reckless act, or a breach of warranty arising under Article 2 of M.G.L. c. 106).

## VI. CONCLUSION

This case should be dismissed as to Alaunus for multiple reasons. As an initial matter, all of the allegations against Alaunus are merely conclusory assertions and the Complaint does not provide Alaunus with adequate notice of the factual basis of the liability asserted. The statement in the Complaint that Alaunus "is a pharmaceutical development company that distributes pharmaceutical products manufactured, compounded, packaged, and sold by Defendants NECC and Ameridose," *Pl. Compl.* at ¶ 11, is not a "fact" which must be taken as true on a 12(b)(6) motion because it is merely a formulaic recitation of the definition of a "manufacturer" and "seller" under the IPLA and the Complaint does not contain any factual allegations *showing* that Alaunus is a "manufacturer" or "product seller" within the meaning of the statute. Plaintiffs do not plead sufficient facts, as opposed to conclusory assertions, to show that Alaunus is vicariously liable for NECC's alleged tortious conduct under an alter-ego liability theory. Each Complaint impermissibly "lumps" NECC, Ameridose, MSM, and Alaunus together and therefore does not provide those defendants with notice as to the specific basis of liability asserted against each individual defendant.

Moreover, the factual content in the Complaint, when taken as true, does not give rise to a plausible inference of liability against Alaunus. There is a true conflict of laws and Indiana law governs because that is the place where the injury occurred and Massachusetts does not have a more significant relationship to the underlying product liability claims in this case. Any claim that Mr. Stout may have had against Alaunus under the IPLA had he survived fails because Plaintiff has not shown that Alaunus is a "manufacturer" or "seller" of the MPA product as defined under the IPLA, or had any involvement whatsoever in that products' compounding, distribution, or marketing. The common law claims for negligence, negligent infliction of emotional distress, breach of express and implied warranties, battery, failure to warn, and loss of consortium are subsumed under the IPLA, and may not be sustained as separate actions against an alleged "manufacturer" or "seller." Even if those claims are not subsumed under the IPLA (which they are), the Complaint fails to plead sufficient facts to establish

a viable claim under any of those theories of liability. In any event, any product liability claim that accrued in favor of Mr. Stout terminated at his death under Indiana's Survival Act, leaving Mrs. Stout with a claim under the IWDA. Given that the Complaint fails to state any viable claim against Alaunus on behalf of the decedent, the loss of consortium and wrongful death claims should be dismissed because Mrs. Stout's claim for damage to the marital relationship is derived from the failed claims asserted by the decedent against Alaunus and the Complaint does not show that Mr. Stout's death was caused by a wrongful act or omission by Alaunus. Similarly, the claim for establishment of a limited fund constructive trust fails because there is no showing of any fraud, breach of fiduciary duty, or any other wrongful conduct by Alaunus. Finally, the claim for class certification fails for lack of predominance of factual and legal issues. For these reasons, the Plaintiff's Complaint woefully fails to state a claim and should be dismissed in its entirety, or at the very least as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6).[24]

Alaunus Pharmaceutical, LLC,
By its Attorney,

Dated: February 25, 2013

*/s/ Ryan Ciporkin*

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[24] Given that Plaintiffs' claims against Alaunus are baseless and that discovery in this case will be massive, Plaintiffs are not entitled to conduct any discovery to cure the defects in their pleading. *See Twombly*, 127 S. Ct. at 1966 (rejecting arguments that a plaintiff should be permitted to proceed with discovery and that case management techniques may be used to weed out baseless claims and ruling that one of the main goals of the plausibility standard is the avoidance of unnecessary discovery and discovery would be massive since the Plaintiff represents a putative class of at least 90 percent of all subscribers to local telephone or high-speed Internet service in the continental United States in an action against America's largest telecommunications firms); *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005) ("something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with `a largely groundless claim' be allowed to `take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value").

**CERTIFICATE OF SERVICE**

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on February 25, 2013 using the CM/ECF system which sent notification of this filing to all ECF registered counsel of record via e-mail generated by the Court's ECF system.

*/s/ Ryan Ciporkin*

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